## REMARKS

**Status of Claims**

Claims 9-24 are pending for examination on the merits.

Claims 9-24 are rejected.

The Examiner acknowledged that the amendments to the specification (title) and drawings were accepted.

## Withdrawn Rejections

The Examiner acknowledged that the following rejections were withdrawn:

(1) the rejections under 35 U.S.C. 112 first paragraph and 112 second paragraph in view of Applicant's claim amendments and arguments; and

(2) the rejections under 35 U.S.C. 103(a) over Els, Invanova and Sakata, in view of Applicant's claim amendments and arguments.

Applicant thanks the Examiner for the withdrawal of the above rejections.

Applicant has amended the claims for clarification purposes and as described below. No new matter has been added.

This Amendment, filed in reply to the Office Action dated February 3, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

## New Objection/Rejections

**I. Claim Objections**

Claim 13 is objected to due to misspelling of the term "aldwehyde" in line 1.

**Applicant's Response**

Claim 13 has been amended in order to correct the self-evident typographical error. Therefore, Applicants respectfully request that the Examiner withdraw this ground of objection.

**II. Claim Rejections under 35 U.S.C. §112, second paragraph**

Claim 13 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contended that claim 13 depends on itself.

**Applicant's Response**

Claim 13 has been amended to be dependent from claim 9.

In addition, claims 9, 11, 12, and 16 have been amended for clarification purposes. No new matter has been added.

Accordingly, Applicants respectfully request that the Examiner withdraw this ground of rejection.

**III. Claim Rejections under 35 U.S.C. §112, first paragraph (Written Description Requirement)**

Claims 9-16 were rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

Citing MPEP § 2163, the Examiner asserted that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The Examiner asserted that the factors considered in the written description requirement are: (1) level of skill and knowledge in the art; (2) partial structure; (3) physical and/or chemical properties; (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function; and the (5) method of making the claimed invention. The Examiner further asserted that disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

On the above grounds, the Examiner contended that, while claim 9 refers to "brain disease other than stroke," it is unclear what "brain disease other than stroke" is, since it was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner contended:

(1) that there is no description of what "brain disease other than stroke" or "brain disease" include;

(2) that no specific disease is mentioned; and

(3) that no explanations and examples are provided.

The Examiner contended that since "brain disease other than stroke" is not the same as "group of other brain diseases" in Figs. 1 and 2, the specification does not provide support for the claim. The Examiner further contended (1) that one skilled in the art would conclude that the inventors were not in possession of the claimed invention since it is not clear what "brain disease other than stroke" is as claimed; and (2) that therefore the claims fail to comply with the written description requirement.

Citing *In re Wilder*, the Examiner contended that the description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention (*In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate")

Based on the above grounds, the Examiner contended that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. Therefore, the Examiner suggested that Applicant describe "brain disease other than stroke" by stating what disease is included or excluded in the group.

**Applicant's Response**

Solely to advance prosecution of the present application, without acquiescing in this ground of rejection, claim 9 has been amended to remove the phrase "or a subject suffering from brain disease other than stroke." Therefore, this ground of rejection has been rendered moot in view of Applicant's claim amendment.

Accordingly, Applicant respectfully request that the Examiner withdraw this ground of rejection.

**IV. Claim Rejections under 35 U.S.C. §112, first paragraph (Written Description Requirement)**

Claims 9-24 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner contended that claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner asserted that the factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988)). Specifically, the Examiner asserted that the court in Wands states "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations."

The Examiner stated that factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Examiner contended that, in the instant case, all the examples (1-2) and Figs. 1 & 2 in the specification compares the measurements of acrolein content and amine oxidase activity between subjects with infarction disorder with healthy/group of other brain disorder, while the infarction disorder (stroke) includes both symptomatic and asymptomatic cerebral infarction, thus the significantly higher measurements is indicative for all infarction disorder not necessarily indicate only asymptomatic cerebral infarction. On this alleged ground, the Examiner contended

that the specification does not provide support for claims 9-24 wherein significantly higher measurements is indicative for all infarction disorders not just for asymptomatic cerebral infarction.

The Examiner contended that given that the specification does not provide support for claims 9-24, an undue quantity of experimentation will be necessary to address the claimed limitation in claims 9-24 to exclude symptomatic cerebral infarction. The Examiner further contended that when the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation, and thus the claims are not enabled.

Based on the above grounds, the Examiner concluded that the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

**Applicant's Response**

Applicants submit that with respect to the phrase "asymptomatic cerebral infarction," the present specification discloses that "[i]n the following examples, the presence of infarction was examined by obtaining head tomographic image with magnetic imaging diagnosis (MRI) with the consent of subjects. As a result, as shown in the following examples, evidence of cerebral infarction was shown in the subjects (i.e., the subjects suffering from) who indicated elevated polyamine levels in the healthy group." (See, US 2008254495 (A1), paragraph [0028]). Therefore, Applicants respectfully submit that a person having ordinary skill in the art, in view of the guidance and examples provided by the present specification, would be able to carry out the claimed inventions without requiring undue experimentation.

Accordingly, the claimed inventions claimed in claims comply with the enablement requirements.

**V. Double Patenting**

Claims 9, 13, 17, 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 of copending Application No. 12/598,125. The Examiner contended that although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim detecting/diagnosing method of asymptomatic cerebral infarction by measuring acrolein/aldehyde compound content and measuring polyamine oxidase activity/content.

In response to the Applicant's arguments filed 12/16/2010, the Examiner contended that new claims (see above rejection) are drawn to the same diagnostic method (because asymptomatic cerebral infarction is one type of stroke and no distinction is made between asymptomatic or symptomatic cerebral infarction) with similar steps, therefore the double patenting rejection is applied.

**Applicant's Response**

In view of the fact that the present application is assigned to KAZUEI IGARASHI, FUENCE CO., LTD, and AMINE PHARMA RESEARCH INSTITUTE (Reel/Frame: 024012/0234 ), whereas the copending U.S. Application No. 12/598,125 is assigned to NATIONAL UNIVERSITY CORPORATION CHIBA UNIVERSITY (Reel/Frame: 019482/0157), and further in view of the fact that the two applications have different inventive entities, Applicant respectfully requests that the Examiner provide Applicant with clarification and guidance for preparing a proper response to the instant ground of rejection.

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In view of the above remarks, it is respectfully submitted that the pending claims 9-24, are in condition for allowance and such action is earnestly solicited. If the Examiner believes that a telephone conversation would help advance the prosecution in this case, the Examiner is respectfully requested to call the undersigned at 973-360-7934. The undersigned also may be contacted via email at lubitb@gtlaw.

## AUTHORIZATION

The Commissioner hereby is authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account 501561.

Respectfully submitted,
For Greenberg Traurig
By

Date: 4/29/11

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